

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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TAKEDA PHARMACEUTICALS	:	
U.S.A., INC.,	:	
	:	
Plaintiff and Counterclaim-Defendant,	:	
	:	C.A. No. 19-2216-RGA
v.	:	
	:	<b>FILED UNDER SEAL</b>
MYLAN PHARMACEUTICALS INC.,	:	
	:	
Defendant and Counterclaim-Plaintiff.	:	
	:	
	:	

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**TAKEDA PHARMACEUTICALS U.S.A., INC.'S OPENING BRIEF  
IN SUPPORT OF ITS  
MOTION FOR SUMMARY JUDGMENT OF NO DAMAGES**

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## **I. INTRODUCTION AND SUMMARY OF ARGUMENT**

Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) respectfully moves for summary judgment of no damages with respect to Mylan Pharmaceuticals Inc.’s (“Mylan”) counterclaim for breach of Section 1.7 of the parties’ November 2017 license agreement (“License Agreement”). In finding that Takeda had breached Section 1.7—but not Section 1.12—of the License Agreement, this Court made clear that Takeda’s only breach was in bringing patent-infringement claims in addition to a breach-of-contract claim, rather than bringing only a breach-of-contract claim. The Court further clarified that Mylan could seek damages only for the harm caused by Takeda’s patent-infringement claim. Nevertheless, Mylan seeks damages for: (i) lost sales<sup>1</sup> for the period of time it alleges it was kept off the market and a period of time thereafter; and (ii) attorney fees for this entire litigation. Mylan has not produced a shred of evidence that any of its alleged lost profits were caused by Takeda’s patent-infringement claims, as opposed to its breach-of-contract claim. Moreover, Mylan has made no attempt to determine which portion of its fees were due solely to Takeda’s patent-infringement claims. These failures are fatal because lost profits and attorney fees are the only damages that Mylan seeks and Mylan has not come forth with any evidence as to either. Thus, Takeda is entitled to summary judgment of no damages.<sup>2</sup>

## **II. NATURE AND STAGE OF PROCEEDINGS**

In December 2019, Takeda filed a complaint (D.I. 2) against Mylan, alleging breach of the License Agreement (Count I) and patent infringement (Counts II-XVIII), and filed a preliminary injunction motion (“PI motion”) (D.I. 12). Following preliminary injunction briefing and an

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<sup>1</sup> This brief uses the terms “lost sales” and “lost profits” interchangeably.

<sup>2</sup> Takeda is separately filing a motion to exclude Mylan’s expert testimony in its entirety under *Daubert* principles and Fed. R. Evid. 702. This Court need not reach the *Daubert* motion in order to grant the present motion for summary judgment.

appeal, the Court denied Mylan’s motion to dismiss (D.I. 154) and subsequent motion for reconsideration (D.I. 162). On December 1, 2020, Mylan filed its answer and counterclaims, asserting an express license defense and two counterclaims for alleged breach of the License Agreement’s covenant not to sue and no interference provisions. D.I. 164. On September 27, 2023, the Court granted Mylan’s summary judgment motion (D.I. 244) and ordered judgment in Mylan’s favor on Takeda’s breach of contract claim (D.I. 245), which also necessarily resolved Takeda’s patent infringement claims.

In a February 7, 2024 Scheduling Order, the Court ordered the parties to file cross-motions for summary judgment regarding the issue of liability concerning Mylan’s counterclaims (to be fully briefed by April 2024), and that the parties should simultaneously conduct discovery on the issue of damages (with discovery ending in November 2024). D.I. 268 ¶¶ 1, 5. The deadline for the completion of expert discovery was later extended to January 8, 2025. D.I. 364.

On December 3, 2024, the Court ruled on the parties’ cross-motions for summary judgment on liability. D.I. 366; D.I. 367. Specifically, the Court held that with respect to Mylan’s First Counterclaim (breach of Section 1.7 of the License Agreement), only Takeda’s assertion of patent infringement—and not Takeda’s assertion of breach of contract against Mylan—breached the License Agreement. D.I. 366 at 9, 12. The Court granted summary judgment to Takeda on Mylan’s Second Counterclaim (breach of Section 1.12). D.I. 366 at 10-13. Accordingly, only Mylan’s First Counterclaim remains in the case, and only as it relates to Mylan’s alleged damages incurred due to Takeda’s patent-infringement claims. D.I. 366 at 9, 12, 13-14.

Takeda now moves for summary judgment of no damages, as Mylan has adduced no evidence demonstrating entitlement to any damages. Mylan has no proof—and the record definitively disproves—that any assertion of patent infringement by Takeda was the but-for cause

of any of Mylan's claimed damages. Therefore, and for the additional reasons explained below, Mylan's claimed damages are barred as a matter of law.

### III. STATEMENT OF FACTS

#### A. Takeda and Mylan Entered Into a License Agreement

In November 2017, Takeda and Mylan entered into agreements, including the Settlement Agreement and License Agreement, that settled the parties' Hatch-Waxman litigation in connection with Mylan's ANDA submitted to FDA for approval of the Mylan ANDA Product.<sup>3</sup> The License Agreement granted Mylan a non-exclusive license to market the Mylan ANDA Product in the United States on a date certain (§ 1.2(a)), or earlier upon the occurrence of certain specified events (§ 1.2(b)-(g)).

Further, the License Agreement contains express language that allows Takeda to enforce the parties' agreement. For example, Section 1.8 states:

(a) Solely with respect to the Mylan ANDA Product and solely for purposes of ***enforcement of this License Agreement*** and the Settlement Agreement executed herewith, Mylan . . . acknowledges that the commercial manufacture, use, offer for sale, sale or importation of the Mylan ANDA Product in the Territory, unless pursuant to the License granted by Takeda hereunder, would infringe one or more of the claims of the Licensed Patents asserted against them in the Litigation by Takeda in connection with the Mylan ANDA Product. Further, solely with respect to the Mylan ANDA Product and solely for purposes of ***enforcement of this License Agreement*** and the Settlement Agreement executed herewith, Mylan . . . acknowledges that the Licensed Patents are valid and enforceable. . . .

(b) Mylan, on behalf of itself and its Affiliates, agrees ***not to challenge*** the infringement, validity, and enforceability of the Licensed Patents solely with respect to the Mylan ANDA Product, . . . .

(License Agreement § 1.8.)<sup>4</sup> Section 1.10 provides an avenue for Takeda to seek immediate injunctive relief if Mylan is in breach of Sections 1.2 and 1.4:

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<sup>3</sup> The Settlement Agreement and License Agreement are attached as Exhibits 2 and 3 to D.I. 273, respectively.

<sup>4</sup> Unless otherwise stated, all ***bold and italicized*** emphasis in this brief is added.

Takeda shall be entitled to *specific enforcement* of the terms and conditions set forth in [Sections] 1.2 and 1.4 of this License Agreement, and shall be entitled to *immediate injunctive relief* to prevent Mylan from marketing the Mylan ANDA Product in breach of [Sections] 1.2 and 1.4 of this License Agreement. Mylan acknowledges that marketing the Mylan ANDA Product in breach of [Section] 1.2 of this License Agreement would cause Takeda *irreparable harm*. Nothing in the preceding sentences shall limit Mylan's ability to seek to recover damages for an improperly issued injunction.

(License Agreement § 1.10.)

Additionally, the License Agreement includes a covenant not to sue (Section 1.7) and a no interference (Section 1.12) provisions. Section 1.7 of the License Agreement states:

Takeda covenants (provided there is no material breach by Mylan) . . . not to sue, assert any claim or counterclaim against, or otherwise participate in any action or proceeding against Mylan or any of its Affiliates . . . *in each case for infringement of any U.S. or foreign patent or patent application owned, licensed or otherwise controlled, now or in the future, by Plaintiff* or any of its respective Affiliates at any time during the term of this Agreement based on or arising from the manufacture, use, sale, offer for sale or importation within the scope of the License, of any of Mylan ANDA Product . . . For any such patent owned, licensed or otherwise controlled, now or in the future, by Plaintiff . . . the foregoing covenant not to sue will be treated as a nonexclusive license solely for the purposes of permitting Mylan and its Affiliates to file and maintain with the FDA a “Paragraph IV Certification” under 21 U.S.C. § 355G)(2)(A)(vii)(IV) (as amended or replaced) with respect thereto.

Section 1.7 does not limit all litigation against Mylan, but only assertions of patent infringement.

## **B. The Present Suit**

### **1. Proceedings Regarding Takeda's Claims Against Mylan**

On December 2, 2019, Takeda sued Mylan for breach of contract (Count One) and patent infringement (Counts Two to Eighteen), where Takeda's patent infringement claims arose out of the same conduct as its breach-of-contract claim—Mylan's November 25, 2019 launch of its ANDA Product. D.I. 2; *see also* D.I. 273 at Ex. 3 § 1.8. On December 5, 2019, Mylan agreed that “[u]ntil the earlier of January 31, 2020, or this Court's decision on Takeda's Motion for a Preliminary Injunction, Mylan . . . hereby agree[s] to immediately cease and desist from engaging

in the sale and distribution of the Mylan ANDA Products.” D.I. 279-6 ¶ 1. On December 5, 2019, Takeda filed its PI motion. D.I. 12. Mylan, in its opposition brief, sought a bond in the event the Court granted Takeda’s PI motion. D.I. 40 at § IV.F. On January 27, 2020, although the Court denied Takeda’s PI motion, it ordered Mylan to “maintain the status quo until January 31, 2020” (“Status Quo Order”), to give Takeda “an opportunity to seek immediate relief” before the Federal Circuit. D.I. 114 at 7. Mylan never sought a bond for the Status Quo Order.

On January 28, 2020, Takeda moved for an injunction pending appeal and an interim injunction during the pendency of Takeda’s motion. Ex. 1<sup>5</sup>, *Takeda Pharm., USA, Inc. v. Mylan Pharm., Inc.*, No. 20-1407, ECF No. 6-1. On January 29, 2020, the Federal Circuit granted Takeda’s motion for an interim injunction and maintained the Status Quo Order pending the Federal Circuit’s consideration of Takeda’s request for an injunction pending appeal. Ex. 2, *id.* at ECF No. 14 at 2. The Status Quo Order remained in effect for more than a month before Mylan filed a motion for bond during the Order’s pendency. Ex. 3, *id.* at ECF No. 49. On March 23, 2020, the Federal Circuit denied Takeda’s motion for injunction pending appeal and Mylan’s motion for bond, and lifted the interim injunction. Ex. 4, *id.* at ECF No. 60 at 2.

The Federal Circuit affirmed the Court’s denial of Takeda’s preliminary injunction motion. *Id.* at ECF No. 60 at 3-4; *Takeda Pharm., USA, Inc. v. Mylan Pharm., Inc.*, 967 F.3d 1339 (Fed. Cir. 2020). Following the preliminary injunction proceedings, this Court denied both Mylan’s motion to dismiss Takeda’s complaint (D.I. 154) and subsequent motion for reconsideration (D.I. 162), finding that discovery was necessary for the Court to be able to construe the License Agreement.

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<sup>5</sup> Exhibits submitted contemporaneously herewith are designated as “Ex. \_\_” and are attached to the Declaration of Porter F. Fleming, Esq. In Support of Takeda Pharmaceuticals U.S.A., Inc.’s Motion for Summary Judgment of No Damages.

On July 8, 2021, the Court bifurcated the case, ordering that the parties conduct discovery only on whether the timing of Mylan’s launch of its ANDA Product was authorized by the License Agreement. D.I. 198. This phase of the case would resolve Mylan’s liability on Takeda’s claim for breach of contract, and, by definition, would also resolve Mylan’s license defense. D.I. 198. “Discovery relating to all other claims and issues (including Takeda’s Claims Two to Eighteen, MPI’s Counterclaims One to Two, and all damages issues) [was] stayed” until the Court’s ruling on whether Mylan’s launch was permitted under the License Agreement. D.I. 198 ¶ 2. The Court later explained that it had bifurcated Takeda’s patent claims from its contract claim because “it seemed likely based on the preliminary injunction proceedings that the patents would never become an issue” and therefore “doing patent discovery would likely be a colossal waste of time and money.” D.I. 265 at 5.

On September 27, 2023, the Court granted summary judgment that Mylan’s launch was permitted by Section 1.2(d) of the License Agreement, and that Mylan therefore did not breach the License Agreement. D.I. 244. Because the Court found that Mylan’s launch was authorized by the License Agreement, the Court recognized that this ruling “necessarily resolved Takeda’s claim[s] for patent infringement in Mylan’s favor.” D.I. 366 at 3.

## **2. Proceedings Regarding Mylan’s Counterclaims**

After the Court granted summary judgment to Mylan on Takeda’s claim, Mylan pursued its two counterclaims. The parties cross-moved for summary judgment on liability, and have concluded fact and expert discovery on damages. During discovery, Mylan made clear that it sought damages only for: (i) lost sales and profits related to Mylan’s ANDA Product; and (ii) costs of suit Mylan expended in defending Takeda’s claims and pursuing counterclaims in this matter.

D.I. 353 Ex. 5 at 6 (Initial Disclosures);<sup>6</sup> D.I. 353 Ex. 9 at 8 (Mylan’s Second Amended Responses and Objections to Interrogatory No. 9).

On December 3, 2024, the Court ruled on the parties’ cross-motions for summary judgment on liability. D.I. 366; D.I. 367. Specifically, with respect to Mylan’s First Counterclaim (alleging breach of Section 1.7), the Court held that only Takeda’s assertion of patent infringement—and not Takeda’s assertion of breach of contract against Mylan—breached Section 1.7 providing that Takeda would not sue Mylan for patent infringement absent a material breach by Mylan. D.I. 366 at 9. In so doing, the Court “note[d] the narrow scope of § 1.7 of the Agreement. It does not limit litigation generally. It limits only ‘case[s] for [patent infringement].’” D.I. 366 at 9 (citing D.I. 218 at Ex. 2, § 1.7). And to leave no doubt, the Court further noted that had Takeda brought only a breach-of-contract claim against Mylan or otherwise sought to enforce the License Agreement without asserting a patent-infringement claim, such action would not “even arguably breach[] § 1.7 of the Agreement.” D.I. 366 at 9.

With regard to Mylan’s Second Counterclaim (alleging breach of Section 1.12), the Court granted summary judgment in favor of Takeda, holding that “§ 1.12 does not extend to lawsuits against Mylan” and that Takeda had not breached Section 1.12. D.I. 366 at 10-13. The Court noted “the specificity with which § 1.7 is written—barring only patent infringement claims, and only in the absence of a material breach” and recognized that Section 1.7 would be rendered “completely unnecessary if Section 1.12 is read to bar all lawsuits that affect Mylan’s efforts to manufacture and market their generic colchicine product.” D.I. 366 at 12-13.

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<sup>6</sup> Takeda uses “attorney fees” and “costs of suit” interchangeably in this brief to refer collectively to attorney fees and associated expenses.

The last expert deposition took place on January 8, 2025. Trial is scheduled to begin on May 27, 2025. D.I. 268 ¶ 10.

#### IV. ARGUMENT

##### A. Legal Standards

Summary judgment is appropriate if there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The moving party may demonstrate entitlement to summary judgment “by pointing out to the district court that there is an absence of evidence supporting the non-moving party’s case.” D.I. 366 at 4 (citation omitted).

“Under Delaware law, the elements of a breach of contract claim are: (1) a contractual obligation; (2) a breach of that obligation by the defendant; and (3) a resulting damage to the plaintiffs.” *Phunware, Inc. v. Excelmind Grp. Ltd.*, 117 F. Supp. 3d 613, 625 (D. Del. 2015) (citation omitted). “It is a basic principle of contract law that remedy for a breach should seek to give the nonbreaching the party the benefit of its bargain by putting that party in the position it would have been but for the breach.” *Genencor Int’l, Inc. v. Novo Nordisk A/S*, 766 A.2d 8, 11 (Del. 2000); *see also Truinject Corp. v. Galderma S.A.*, 694 F. Supp. 3d 491, 500 (D. Del. 2023) (quoting *eCommerce Indus., Inc. v. MWA Intelligence, Inc.*, C.A. No. 7471-VCP, 2013 WL 5621678 at \*44 (Del. Ch. Sept. 30, 2013)) (same). In other words, a plaintiff must demonstrate “both the existence of damages provable to a reasonable certainty, and that the damages flowed from the defendant’s violation of the contract.” *37celsius Capital Partners. L.P. v. Intel Corp.*, No. 20-CV-621, 2024 WL 4144199, at \*7 (E.D. Wis. Sept. 10, 2024) (applying Delaware law). “In assessing damages for breach of contract and related claims, it is therefore important to consider how the positions of the parties would differ in the ‘but-for’ world—i.e., the hypothetical world that would exist if the Agreement had been fully performed.” *Id.*; *see also Mattern & Assocs., L.L.C. v. Seidel*, 678 F. Supp. 2d 256, 272 (D. Del. 2010) (recognizing that a party seeking

attorney fees “bears the burden of establishing the reasonableness of both the time expended and the hourly rates”); D.I. 346 at 1 (“Mylan has the burden of proof on the reasonableness of its requested fees.”).

If a plaintiff does not have evidence sufficient for a fact-finder to conclude that the defendant’s breach of contract was the but-for cause of the plaintiff’s alleged damages, it is appropriate to grant summary judgment of no damages. *Truinject*, 694 F. Supp. 3d at 500; *37celsius*, 2024 WL 4144199, at \*7. In the context of a covenant not to sue, damages are recoverable only for the part of the lawsuit that breached the covenant—not for portions of the lawsuit that are permissible. D.I. 366 at 9, 12; *see also Securus Techs., Inc. v. Global Tel\*Link Corp.*, No. 3:13-CV-03009-K, 2015 WL 6956771, at \*2 (N.D. Tex. Nov. 2, 2015) (recognizing that “[w]hen a party breaches a covenant not to sue, the damages caused by that breach are the costs and expenses of defending the litigation that the parties agreed would not happen under the covenant not to sue” and granting summary judgment of no damages due to failure of proof).

## **B. Takeda Is Entitled to Summary Judgment of No Lost Profits**

### **1. Takeda’s Claims of Patent Infringement Were Not the “but-for” Cause of Mylan’s Claimed Lost Profits**

As discussed above, this Court held that only Takeda’s assertion of patent infringement—and not Takeda’s assertion of breach of contract against Mylan—breached the License Agreement. D.I. 366 at 9, 12-13. Mylan has come forth with no evidence whatsoever that its alleged lost profits were causally related to Takeda’s assertion of patent infringement (i.e., the only activity by Takeda that the Court found was impermissible under the License Agreement). Nor could it. Mylan’s alleged lost profits are premised on Mylan’s claimed inability to sell its colchicine product due to Takeda’s preliminary injunction proceedings. D.I. 353 Ex. 9 at 8. Yet, Takeda’s motion for a preliminary injunction hinged on Takeda’s assertion that Mylan breached Sections 1.2 and 1.4 of

the License Agreement by launching its generic colchicine product before the time permitted by the License Agreement. D.I. 13 at 14-15. This Court recognized this in its ruling on the preliminary injunction motion. *See* D.I. 114 at 3 (“The critical issue here is whether Section 1.2(d) of the License Agreement permits Mylan to launch its generic colchicine product.”). Moreover, in showing irreparable harm—one prerequisite to establishing entitlement to injunctive relief—Takeda relied only on Section 1.10 of the Agreement, which stipulated that Takeda would suffer irreparable harm in the event Mylan breached Sections 1.2 or 1.4, and that such breach would entitle Takeda to “immediate injunctive relief.” (License Agreement § 1.10.)

Had Takeda been seeking injunctive relief for Takeda’s patent claims separately from its contract claim, Takeda would have been required to present detailed economic evidence of irreparable harm. Indeed, the Federal Circuit held that “[w]ithout the stipulation of irreparable harm, Takeda makes no credible assertion that it cannot be compensated by monetary damages.” *Takeda Pharm. U.S.A., Inc. v. Mylan Pharm. Inc.*, 967 F.3d 1339, 1349 (Fed. Cir. 2020). It is only when the parties agree to irreparable harm (as the parties did in Section 1.10 of the License Agreement) that a separate analysis is not required. *See Amgen Inc. v. Apotex Inc.*, 827 F.3d 1052, 1060 (Fed. Cir. 2016) (assuming irreparable harm when the parties stipulated to its existence). It is only because of Takeda’s breach-of-contract claim that Takeda was able to streamline the preliminary-injunction proceedings to focus on the proper interpretation of the License Agreement.

Unsurprisingly, Mylan has failed to come forward with any evidence that Mylan’s alleged lost profits had anything to do with Takeda’s patent-infringement claims specifically. To the contrary, Mylan’s expert witness, Mr. Ivan Hofmann, simply assumes that Takeda’s lawsuit, as a whole, caused Mylan to lose profits. Indeed, Mr. Hofmann admitted that he simply assumed that Takeda’s breach of contract was the but-for cause of all of Mylan’s claimed damages. Ex. 5,

Hofmann Dep. Tr. 8:10-22; D.I. 349-1, Hofmann Rpt. (hereafter “Hofmann Rpt.”) ¶ 11 (stating that he was “asked to assume that liability is found in favor of Mylan and against Takeda related to Takeda’s breaches of the License Agreement” and that he had “no opinion on the claims of breach of the License Agreement brought by Mylan against Takeda”); Hofmann Rpt. ¶ 22 (stating his assumption that Takeda breached both Sections 1.7 and 1.12 of the License Agreement); Hofmann Rpt. ¶¶ 22-23 (opining, in relevant part, that “Takeda’s breaches” of Sections 1.7 and 1.12 caused Mylan “lost sales of Mylan’s colchicine tablets and profits therefrom during the period of December 5, 2019 through March 22, 2020 and for the period on and post-dating Mylan’s re-launch of its colchicine product on March 23, 2020 due to Mylan being wrongfully prevented from selling its colchicine tablets and losing its first-mover advantage”). And Mr. Hofmann candidly admitted that he made no attempt to differentiate the damages allegedly caused by: (i) breach of Section 1.7 of the License Agreement (i.e., Mylan’s claim that Takeda’s patent-infringement claims caused damages); and (ii) Takeda’s alleged breach of Section 1.12 of the License Agreement based on the entire litigation (which this Court has held on summary judgment is not a viable theory). Ex. 5, Hofmann Dep. Tr. 11:17-13:13. Indeed, Mr. Hofmann went as far as to say that any attempt at apportionment would be “a distinction without a difference[.]” Ex. 5, Hofmann Dep. Tr. 11:21. As explained above, the only basis for any court-imposed pause in sales was Takeda’s breach-of-contract claim against Mylan. Accordingly, because there is no evidence that Takeda’s patent-infringement claims were the but-for cause of any of Mylan’s alleged lost profits, summary judgment of no lost profits is warranted.

**2. Mylan’s Additional Failures of Proof Further Entitle Takeda to Summary Judgment of No Lost Profits**

Because Takeda’s assertion of patent infringement was not the but-for cause of any of Mylan’s lost profits as explained above, summary judgment of no lost profits should be granted

on that basis, and the Court need not consider the additional reasons for summary judgment of no lost profits explained herein. Nevertheless, Takeda explains below several additional bases for why summary judgment of no lost profits is appropriate.

**a. Mylan’s Claimed Lost Profits Are Not Cognizable Under Delaware Law**

Delaware law greatly circumscribes the availability of consequential damages. “Damages are consequential when the breaching party’s actions cause the non-breaching party to suffer a loss of profit on a collateral business arrangement.” *Truinject*, 694 F. Supp. 3d at 500 (citing *Frank Invs. Ranson, LLC v. Ranson Gateway, LLC*, No. CV 11101-VCN, 2016 WL 769996, at \*13 (Del. Ch. Feb. 26, 2016)); *see also Crowell Corp. v. Himont USA, Inc.*, No. 86C-11-125, 1994 WL 762663, at \*3 (Del. Super. Ct. Dec. 8, 1994) (cited in *37celsius*, 2024 WL 4144199, at \*8 (“Under Delaware law, consequential damages in the form of good will, lost future profits, and lost customers are not awarded in breach of contract actions. The Delaware courts have consistently found these damages to be speculative in nature, and; therefore, have barred recovery for them.”)); *Truinject*, 694 F. Supp. 3d at 500 (“Consequential damages are recoverable only if the damages were a reasonably foreseeable probable result of the breach at the time the contract was entered.”).

The foreseeable damages for breach of a covenant not to sue for patent infringement—the only conduct that this Court found to be in breach of the License Agreement—is attorney fees. *See* D.I. 366 at 13-14 (concluding that under Delaware law, breach of a covenant not to sue entitles the non-breaching party to attorney fees in defending the part of the litigation that was impermissible). There is no evidence that at the time the License Agreement was entered into, the parties (and especially Takeda) could have foreseen that the assertion of patent infringement would cause the lost profits that Mylan is seeking here. Indeed, Mr. Hofmann conducted no analysis as to whether Mylan’s claimed damages were reasonably foreseeable at the time the parties entered

into the License Agreement. Rather, Mr. Hofmann simply assumed that Takeda's alleged breach of contract caused all of Mylan's claimed lost profits, and assumed that such lost profits were cognizable as damages. Ex. 5, Hofmann Dep. Tr. 104:24-106:8. Accordingly, Mylan's claimed lost profits are, at most, consequential damages that are not recoverable. For this reason, summary judgment of no lost profits is required. If Takeda prevails on this point, the Court need not reach the additional grounds for summary judgment of no lost profits discussed below.

**b. Takeda Was Not the Cause of Any Lost-Profits Damages from December 5, 2019 to January 27, 2020**

Mylan claims lost profits between December 5, 2019 and January 27, 2020. D.I. 349-1, Hofmann Rpt. ¶ 16. But during this period of time, Mylan had explicitly agreed to refrain from further sales until the earlier of: (i) the Court's ruling on Takeda's preliminary-injunction motion; or (ii) January 31, 2020. D.I. 279-6 ¶ 1. "Success on a breach of contract claim requires the plaintiff to demonstrate with reasonable certainty that defendant's breach caused the loss." *Active Day OH, Inc. v. Wehr*, C.A. No. N22C-08-064 SKR CCLD, 2024 WL 3201167, at \*4 (Del. Super. June 27, 2024) (internal quotation marks omitted).<sup>7</sup> It was Mylan's voluntary agreement that led to Mylan's alleged lost sales during this period and not Takeda's breach of Section 1.7. Thus, Mylan's lost sales cannot be the basis for damages against Takeda. Therefore, the Court should grant summary judgment of no lost profits from December 5, 2019 to January 27, 2020.

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<sup>7</sup> In *Active Day OH*, although the Delaware Superior Court held that the plaintiff need not come forward with evidence of causation on summary judgment as per the Delaware Superior Court's rules governing summary judgment, Federal Rule of Civil Procedure 56 governs the summary-judgment standard in federal court. *See, e.g., Morello v. Kenco Toyota Lift*, No. 09-4412, 2015 WL 1400582, at \*3 (E.D. Pa. Mar. 26, 2015) (recognizing that federal courts sitting in diversity must apply Federal Rule of Civil Procedure 56, and not state-court rules of procedure, in deciding summary-judgment motions); *Aleynikov v. Goldman Sachs Grp., Inc.*, No. 12-5994 (KM), 2012 WL 6603397, at \*16 (D.N.J. Dec. 14, 2012) ("This Court is applying Delaware substantive law. It cannot, however, consistent with the doctrine of *Erie R. Co. v. Tompkins*, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938), conduct a state summary proceeding within this federal action[.]")

**c. Mylan Cannot Recover Lost Profits Between January 28, 2020 and March 23, 2020**

From January 28, 2020 to March 23, 2020, Mylan was subject to an interim injunction by the Federal Circuit. D.I. 366 at 3. No bond was ever set by this Court nor by the Federal Circuit for the period that Status Quo Order remained in effect. It is well-established that “a [party] wrongfully enjoined has recourse *only* against the bond.” *Sprint Commc’ns Co. v. CAT Commc’ns Int’l, Inc.*, 335 F.3d 235, 240 (3d Cir. 2003). Mylan’s attempt to seek damages between January 28, 2020 and March 23, 2020 is nothing more than an attempt to recover damages from what it believes is an improperly issued injunction, and is a thinly veiled effort to circumvent Fed. R. Civ. 65(c). Had Mylan wanted to protect itself against such an injunction, it should have timely sought a bond. Third Circuit law is clear that retroactively increasing the amount of an injunction bond is improper. *Id.* at 240; *AstraZeneca LP v. Breath Ltd.*, 542 F. App’x 971, 983 (Fed. Cir. 2013) (“[T]he Third Circuit would consider improper an increase to cover past damages”). “Wrongfully enjoined parties may *only* recover in excess of the bond where the party seeking the injunction engaged in bad faith or fraud.” *Takeda Pharm., U.S.A., Inc. v. West-Ward Pharm. Corp.*, No. 14-1268-RGA, 2018 WL 6529289, at \*3 (D. Del. Nov. 12, 2018). Accordingly, Takeda is entitled to summary judgment of no lost profits between January 28, 2020 and March 23, 2020.

**d. Mylan Cannot Recover Lost Profits Between March 24, 2020 and December 31, 2021**

Mylan’s alleged lost profits from March 24, 2020 to December 31, 2021—after the Federal Circuit’s injunction was lifted—are entirely speculative and unforeseeable. As explained *supra* with respect to Mylan’s claims of lost profits in general, lost profits constitute consequential damages, and are recoverable only if reasonably foreseeable to the breaching party at the time the parties entered into the contract. Mylan has come forward with no evidence whatsoever that it would have been foreseeable that Takeda’s assertion of patent infringement in 2019 would cause

Mylan to lose profits even after any injunction was lifted. Accordingly, summary judgment is warranted.

### C. Takeda Is Entitled to Summary Judgment of No Attorney Fees

#### 1. There Is No Evidence that Mylan Incurred Any Attorney Fees as a Result of Defending Takeda's Patent-Infringement Claims Separate from Defending Takeda's Breach-of-Contract Claim

As noted above, Delaware contract law permits recovery only for damages that “flowed from the defendant's violation of the contract.” *37celsius*, 2024 WL 4144199, at \*7; *Genencor*, 766 A.2d at 11 (recognizing that damages under Delaware contract law are to “put[] th[e] [nonbreaching] party in the position it would have been but for the breach”). The U.S. Supreme Court has outlined the appropriate analysis to be applied when a party is entitled to attorney fees for some—but not all—of the claims in a case. For example, it analyzed how to award fees to a civil-rights defendant where: (i) the defendant was entitled to recover fees for the plaintiff's frivolous claims; but (ii) the plaintiff had asserted both frivolous and nonfrivolous claims in the litigation. *Fox v. Vice*, 563 U.S. 826, 829 (2011). The Supreme Court held that in such a case, the defendant is entitled “to recover reasonable attorney's fees incurred because of, but only because of, a frivolous claim[,]” i.e., “only the portion of [the defendant's] fees that he would not have paid but for the frivolous claim.” *Id.* at 836. It further explained that “if the defendant would have incurred [the claimed] fees anyway, to defend against *non*-frivolous claims, then a court has no basis for transferring the expense to the plaintiff.” *Id.* (emphasis in original). Therefore, the defendant may not be awarded fees if, for example, “a defendant's attorney conducts a deposition on matters relevant to both a frivolous and a non-frivolous claim—and more, that the lawyer would have taken and committed the same time to this deposition even if the case had involved only the non-frivolous allegation.” *Id.*; *see also Goodyear Tire & Rubber Co. v. Haeger*, 581 U.S. 101,

108-09 (2017) (holding that the same but-for-causation principle applies to the award of attorney fees under a court’s inherent sanctioning power).

This principle mandates summary judgment of no attorney fees here. The Court made clear that Takeda’s only breach of the License Agreement was its assertions of patent infringement in its Complaint, and that Takeda’s contract claim would not “even arguably breach[] § 1.7 of the Agreement.” D.I. 366 at 9. Therefore, Mylan would be entitled to recover attorney fees only for costs of suit incurred solely due to Takeda’s patent-infringement claims. In other words, Mylan cannot recover fees that would have been incurred in defending Takeda’s permissible breach-of-contract claim even absent Takeda’s assertions of patent infringement. Mylan’s expert has made clear that Mylan would have incurred the same fees with or without Takeda’s allegations of patent infringement. Indeed, Mylan’s expert opines that “[t]here is no appropriate allocation between Mylan’s ‘patent defense’ expenses and ‘breach of contract’ expenses because Mylan’s primary defense to Takeda’s patent infringement claims was that it did not breach its contract with Takeda[,]” and that “the two defenses are the same such that allocation among them is both illogical and impracticable.” Ex. 6, Expert Witness Report of James J. Leonard, Esq. (“Leonard Rpt.”) ¶ 10; *see also id.* ¶ 29 (opining that Mylan’s invoices provide “no legitimate reason or rationale for making [an] apportionment between [Mylan’s] defense of [patent infringement and breach of contract]”); *id.* ¶ 30 (recognizing that “Mylan’s defense to [Takeda’s contract claim and patent claims] was identical”); *id.* ¶ 31 (“[Both the parties and the Court understood that Mylan’s defense to Takeda’s patent infringement and breach of contract claims were the same and would require the same work.”); *id.* ¶ 32 (opining that “any effort to engage in such apportioning would be folly” because “[o]ne cannot reasonably review the fee invoices and parse out what percentage or specific entries might be related to one or the other defense because it was the same defense”

and that there are “no discernible differences between the defense work for either count”). In other words, Mylan acknowledges that it would have incurred the same attorney fees even if Takeda had brought a breach-of-contract claim only. This admission requires summary judgment of no attorney fees.

In sum, Mylan has offered no evidence that Takeda’s patent-infringement claims were the but-for cause of any of Mylan’s claimed attorney fees. Indeed, Mylan’s own expert repeatedly opines the opposite: that Mylan would have incurred the same fees even if Takeda had asserted only its breach-of-contract claim. And Mylan’s in-house counsel recognizes Takeda’s position “that MPI is not entitled to damages in defending against Takeda breach of contract claim” but makes no suggestion that Mylan incurred any damages attributable solely to Takeda’s patent-infringement claims. Ex. 7, Declaration of Thomas Jenkins, Esq. ¶ 16 n.2. The Court should grant summary judgment that Mylan may not recover its claimed costs of suit.

## **2. Separately, Mylan Is Not Entitled to Any Attorney Fees Incurred in Pursuing Its Counterclaims**

Further, Mylan is not entitled to recover attorney fees for pursuit of its counterclaims because the counterclaims were not part of its defense against Takeda’s patent-infringement claims. It was Mylan’s voluntary choice to pursue its counterclaims, rather than Takeda’s conduct, that was the proximate cause of these attorney fees. Accordingly, awarding Mylan attorney fees for pursuing its counterclaims would violate the American Rule.<sup>8</sup> “Delaware law follows the American Rule, under which litigants are generally responsible for paying their own litigation

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<sup>8</sup> Takeda recognizes the Court’s ruling that the American Rule does not prevent Mylan from recovering attorney fees for defending Takeda’s patent-infringement claims. D.I. 366 at 13-14. However, the Court had no occasion in that ruling to consider whether the American Rule bars Mylan from recovering attorney fees incurred in pursuing its counterclaims, as opposed to fees incurred in defending patent-infringement claims.

costs.” *DeMatteis v. RiseDelaware Inc.*, 315 A.3d 499, 508 (Del. 2024); *Mahani v. Edix Media Grp., Inc.*, 935 A.2d 242, 245 (Del. 2007) (“Under the American Rule and Delaware law, litigants are normally responsible for paying their own litigation costs. An exception to this rule is found in contract litigation that involves a fee shifting provision.”). The License Agreement has no fee-shifting provision.

No exception to the American Rule is applicable here. When a party is entitled to attorney fees for breaching a covenant not to sue, attorney fees are recoverable only for the nonbreaching party’s expenditures on that impermissible litigation, and not for the nonbreaching party’s pursuit of its counterclaim for attorney fees. *Princeton Digital Image Corp. v. Off. Depot Inc.*, No. 13-239-LPS, 2017 WL 10765194, at \*5 (D. Del. Aug. 1, 2017) (recognizing the same under New Jersey law and collecting cases, and recognizing that the American Rule would bar an award of attorney fees incurred in pursuing a counterclaim for breach of a covenant not to sue); *Vianet Grp. PLC v. Tap Acquisition, Inc.*, NO. 3:14-CV-3601-B, 2016 WL 4368302, at \*9 (N.D. Tex. Aug. 16, 2016) (recognizing, under Texas law, that “parties may recover attorneys’ fees from prior litigation as damages, but may not recover subsequent fees incurred prosecuting claims for the prior fees”); *see also N.Y. Pizzeria, Inc. v. Syal*, No. 3:13-CV-00335, 2017 WL 9472180, at \*1 (S.D. Tex. Oct. 20, 2017) (recognizing that even where attorney fees are available as damages for breach of a covenant not to sue, the nonbreaching party “still cannot recover fees for his counterclaim”). In other words, courts recognize that “[w]hen a covenant not to sue is used offensively in a counterclaim for breach of contract, the counterclaimants’ attorneys’ fees cannot be considered actual damages, but are incidental costs of litigation.” *Prospect Energy Corp. v. Dallas Gas Partners, LP*, 761 F. Supp. 2d 579, 595-96 (S.D. Tex. 2011) (applying New York law); *see also Securus*, 2015 WL 6956771, at \*2 (recognizing that “[w]hen a party breaches a covenant

not to sue, the damages caused by that breach are the costs and expenses of defending the litigation that the parties agreed would not happen under the covenant not to sue” and granting summary judgment of no damages due to failure of proof). Moreover, it would be especially improper to award Mylan attorney fees on its counterclaims where—as here—Mylan lost its Second Counterclaim on summary judgment, and Mylan has failed to identify any attorney fees that it expended solely on its First Counterclaim.

In sum, Mylan, as a matter of law, cannot recover attorney fees or other costs of suit that it expended in pursuing its counterclaims. Summary judgment is therefore warranted.

**3. If This Court Does Not Grant Summary Judgment of No Attorney Fees, Takeda Is Entitled to Summary Judgment that Mylan’s Attorney Fees Are Recoverable at Delaware Rates, Not New York Rates**

Although the Court need not reach the issue if it grants Takeda summary judgment of no attorney fees, Takeda is entitled to summary judgment that any attorney fees are recoverable at Delaware rates, not higher New York rates. “It is well-established under Delaware law that the measure of damages is attenuated by the principle that the injured party is required to mitigate damages, regardless of whether mitigation is expressly prescribed in the underlying contract.”

*SLH Gen. Contractor, Inc. v. Ambience Inc.*, No. CPU4-19-001661, 2020 WL 1130325, at \*6 (Del. Common Pleas Mar. 4, 2020). Here, Mylan hired Delaware counsel as well as out-of-state counsel (primarily based in New York), and it is undisputed that Delaware counsel’s rates are significantly lower than that of Mylan’s out-of-state counsel. Ex. 8, O’Connor Rpt. Ex. H (comparing the rates of Mylan’s Delaware counsel and Mylan’s out-of-state counsel). Mylan’s Delaware counsel was well-equipped to handle this case, which was primarily based on Delaware contract law. Indeed, even in the context of patent-infringement suits, this Court has held, in awarding attorney fees, that Delaware rates apply. *E.g., Vehicle Interface Techs., LLC v. Jaguar Land Rover N. Am., LLC*, No. 12-1285-RGA, 2016 WL 3436396, at \*3 (D. Del. June 15, 2016) (“The forum in this case is

Delaware. The applicable rates in this matter are, therefore, the prevailing market rates of Delaware intellectual property attorneys. The limited exception to the forum rate rule does not apply because a number of Delaware attorneys can, and do, capably litigate patent matters as lead counsel.”). Similarly, when attorney fees are awarded in contract litigation, “Delaware courts consider the factors set forth in the Delaware Lawyers’ Rules of Professional Conduct,” including “(3) the fee customarily charged in the locality for similar legal services[.]” *Cignex Datamatics, Inc. v. Lam Research Corp.*, No. 17-320 (MN), 2022 WL 4548630, at \*1 (D. Del. Sept. 29, 2022). This aligns with decisions of Delaware state courts, which look to Delaware rates in assessing the reasonableness of attorney fees. *See, e.g., C&D Contractors, Inc. v. McLaughlin*, No.: N22A-04-002 FJJ, 2023 WL 1527396, at \*3 (Del. Super. Feb. 3, 2023) (finding that counsel had “failed to demonstrate the rates it charged are consistent with those customarily charged in the locality for similar legal services”); *Weddle v. BP Amoco Chem. Co.*, No. CV N18A-06-004 ALR, 2020 WL 5049233, at \*3 (Del. Super. Ct. Aug. 26, 2020) (finding no evidence “whether the rate charged for paralegal services aligns with the customary rates for such services in Delaware”).

There is no evidence that Mylan’s Delaware counsel could not have competently and completely handled this litigation, which is based on Delaware contract law. Accordingly, Mylan’s use of New York counsel constitutes a failure to take reasonable efforts to mitigate its damages. Therefore, should the Court not grant summary judgment of no attorney fees, it should hold that Mylan’s recovery of attorney fees must be at Delaware rates, rather than New York rates.

## **V. CONCLUSION**

For the foregoing reasons, Mylan’s claims for lost profits and attorney fees fail as a matter of law because Mylan has not come forward with evidence that would permit a reasonable jury to award such damages. Because lost profits and attorney fees are the only damages that Mylan seeks, the Court should grant summary judgment of no damages.

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*Respectfully Submitted by*

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**CERTIFICATE OF SERVICE**

I, Francis DiGiovanni, hereby certify that on January 24, 2025, Takeda Pharmaceuticals U.S.A., Inc.'s Opening Brief in Support of Its Motion for Summary Judgment of No Damages was electronically filed with the Clerk of the Court using CM/ECF, which will send notification to the registered attorney(s) of record that the documents have been filed. I further certify that on the same day, a copy of these documents was electronically mailed to the registered attorneys of record.

*/s/ Francis DiGiovanni*  
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